K014248
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Section 20.

510(k) Summary of Safety and Efficacy

Date:

December 31, 2001

Submission by:

UroGyn Ltd.
Diamond Tower (26th Floor)
3A Jabotinski Street
Ramat Gan 52520
Israel
Telephone: 972-3-6122254
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Contact Person:

Erez Adiv
Telephone: 972-5-3696076

Name of Device:

DND 202™ Manual Urological Digital Needle Driver

Classification:

21 CRF 884.4530 Obstetric-gynecologic specialized manual instrument.

Regulatory Class:

Class II.

Product Code:

KNA – Obstetricgynecological specialized manual instrument.

Intended Use:

The general purpose of the device as defined in 21 CRF 884.4530:
An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance.

Indication for Use:

The UroGyn DND 202™ Manual Urological Digital Needle Driver is indicated for use during surgical treatment of Pelvic organ prolapse/vaginal prolapse and is equivalent to the currently employed procedure, which is performed with the Deschamps™ device, distributed by BEI Medical Systems Corporation.

The UroGyn DND 202™ device is a surgical tool, consisting of a plastic thimble connected to an operating box. The thimble element of the device contains a surgical needle and a cartridge preloaded with suture material.
The DND 202™ is mounted on the surgeon's index finger and controlled externally. DND 202™ allows the surgeon to operate guided by palpation only. The device is used to anchor the suture material to dense connective tissue at the hipbone during Bladder Neck Suspension for the treatment of Urinary Incontinence or Pelvic Organ Prolapse. The vaginal mucosa is open through surgical incision and the surgeon's finger, with the thimble of the DND 202 mounted on it, is placed through the incision to palpate the desired anatomical structure. The device is then operated externally by the other hand causing the projection of the surgical needle into the tissue. The needle reaches the opposite side of the device and retrieves the suture material from the cartridge. A reverse motion of the needle with the suture material hooked at the tip of the needle retracts the needle back into its housing. The surgeon remove his hand with the device out of the vagina, release the suture material from the needle and ends up with two ends of the suture material anchored to the target connective tissue and ready for tying.

Conclusions:

From UroGyn's experience we believe that the UroGyn design offers an equally effective alternative to the DND 101™ device and/or the Deschamps™ device for the treatment of female vaginal prolapse. Furthermore, as a minimally invasive procedure, we also believe that it presents equal safety to the patient and surgeon.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2002

Mr. Erez Adiv
Consultant
UroGyn Ltd.
Diamond Tower (26th Floor)
3A Jabotinski Street
Ramat Gan 52520
ISRAEL

Re: K014248
Trade/Device Name: Urogyn DND 202™ Manual Urological Digital Needle Driver
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: 85 KNA
Dated: December 15, 2001
Received: December 26, 2001

Dear Mr. Adiv:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 19.

Indication For Use Statement

510(k) Number (if known): ~~K03~~ K014248

Device Name: **DND 202™ Manual Urological Digital Needle Driver**

Indication For Use:

An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance.

The UroGyn DND 202™ Manual Urological Digital Needle Driver is indicated for use during surgical treatment of vaginal prolapse.

(PLEASE DO NOT WRITE BELOW THE LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Krause

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014248